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Dkt. 0575/59167-A-PCT-US/JPW/BJA

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : David J. Pinsky
U.S. Serial No. : 10/049,320 Examiner: S.-L. Chen
Filed : February 6, 2002 Group Art Unit: 1632
For : CD39/ECTO-ADPase FOR TREATMENT OF
THROMBOTIC AND ISCHEMIC DISORDERS

1185 Avenue of the Americas
New York, New York 10036
July 7, 2004

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

COMMUNICATION IN RESPONSE TO MAY 21, 2004 OFFICE ACTION AND
PETITION FOR ONE MONTH EXTENSION OF TIME

This Communication is submitted in response to a May 21, 2004 Office Action issued in connection with the above-identified application. A response to the May 21, 2004 Office Action was due June 21, 2004. Applicant hereby petitions for a one month extension of time. The fee for a one month extension of time for a small entity is FIFTY FIVE DOLLARS (\$55.00), and a check for this amount is enclosed. Applicant has previously established small entity status. With a one month extension of time a response is now due July 21, 2004. Accordingly, this response is being timely filed.

Restriction Requirement Under 35 U.S.C. §121

In the May 21, 2004 Office Action, the Examiner stated that restriction to one of the following inventions is required under 35 U.S.C. §121 and §372:

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- I. Claims 1, 2, 7, 9-13 and 34-36, drawn to a method for treating or preventing stroke in a human subject susceptible to intracerebral hemorrhaging comprising administering to the human subject a CD39 polypeptide having the sequence of SEQ ID No. 1 or active fragment thereof so as to inhibit ADP-mediated platelet aggregation without increasing incidence of intracerebral hemorrhage.
- II. Claims 17-20 and 22-24, drawn to a method for testing a compound by administering the compound to a CD39-deficient mouse model, measuring stroke outcome, the incidence of intracerebral hemorrhage in the mouse, and measuring platelet deposition in ischemic tissue in the mouse.
- III. Claims 27-33, drawn to a method for treating an ischemic disorder in a subject comprising administering to the subject a CD39 polypeptide (SEQ ID No. 1) or an active fragment thereof to inhibit ADP or ATP mediated platelet aggregation or leukocyte accumulation so as to treat the ischemic disorder in the subject.

The Examiner stated that the inventions are distinct, each from the other because of the following reasons:

The Examiner stated that inventions of groups I-III do not relate to a single inventive concept under PCT Rule 13.1 because they lack the same or corresponding special technical features. The Examiner stated that the "special technical feature" for group I is treating or preventing stroke in a human subject susceptible to intracerebral hemorrhaging by using a CD39 polypeptide. The Examiner further stated that the "special technical feature" for group II is testing a compound by administering the compound to a CD39-deficient mouse model and measuring the effect of said compound. The Examiner also stated that the "special technical feature" for group III is treating an ischemic disorder in a subject comprising administering to the subject a CD39 polypeptide. The Examiner stated that each of groups I-III has a "special technical

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feature" not required for the other groups and that they do not share a common special technical feature. The Examiner stated that, thus, groups I-III do not relate to a single general inventive concept under PCT Rule 13.1.

In response to this restriction requirement, applicants hereby elect, with traverse, to prosecute the invention of Examiner's Group III, drawn to a method for treating an ischemic disorder in a subject comprising administering to the subject a CD39 polypeptide (SEQ ID No. 1) or an active fragment thereof.

35 U.S.C. §121

Applicants note that 35 U.S.C. §121 states, in part, that "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require application to be restricted to one of the inventions." [Emphasis added]. Applicants request that the restriction requirement be withdrawn in view of the fact that the claims of Groups I-III are not independent.

Under M.P.E.P. §802.1, "independent" means "there is no disclosed relationship between the subjects disclosed, that is, they are unconnected in design, operation, and effect...". The claims of Group I-III are related in that they are drawn to similar compounds, compositions, and methods of use. All of the methods relate to treating or preventing an ischemic disorder in a subject.

Applicants therefore respectfully assert that two or more independent and distinct inventions have not been claimed in the subject application because the groups are not independent

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under M.P.E.P. §802.01. Therefore, restriction is improper under 35 U.S.C. §121.

Additionally, applicants point out that under M.P.E.P. §803, the Examiner must examine the application on the merits, even though it includes claims to distinct inventions, if the search and examination of an application can be made without serious burden. There are two criteria for a proper requirement for restriction, namely (1) the invention must be independent and distinct; AND (2) there must be a serious burden on the Examiner if restriction is not required.

Applicants maintain that there would not be a serious burden on the Examiner if restriction were not required. A search of prior art with regard to any of Groups I-III would necessarily identify art for the other Groups. Since there is no serious burden on the Examiner to examine Groups I-III in the subject application, the Examiner must examine the entire application on the merits. More specifically, applicants maintain that a search of prior art with regard to Group III would necessarily identify art for the Group I.

PCT Rule 13.1

Applicants note that Groups I and III are both of the same category of claim, i.e. a method, and that both claim Groups share the "special technical feature" of treating an ischemic disorder with a CD39 polypeptide. Applicants note that the ischemic disorder in claim Group I is stroke. Accordingly, Groups I and III form a single general inventive concept under PCT Rule 13.1.

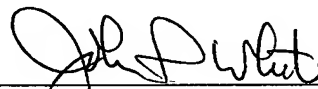
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Applicants maintain that claims 1, 2, 7, 9-13, 17-20, 22-24, 27-33, and 34-36 define a single inventive concept. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the restriction requirement and examine claims 1, 2, 7, 9-13, 17-20, 22-24, 27-33, and 34-36 on the merits.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicant's undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee, other than the enclosed \$55.00 fee for a one month extension of time, is deemed necessary in connection with the filing of this Communication. If any such fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

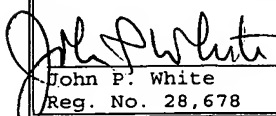
Respectfully submitted,



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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:

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